

I. AMENDMENTS TO THE CLAIMS

This Listing of Claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims

Claim 1 (Currently amended): A pharmaceutical formulation comprising:
a substrate comprising one therapeutic agent consisting of an opioid antagonist;
the substrate overcoated with a diffusion barrier coating comprising an anionic polymer and a
plasticizer coated over said substrate; and
a coating comprising a hydrophobic material and an erosion-promoting agent coated over said diffusion barrier coating.

Claim 2 (Currently amended): The pharmaceutical formulation of claim 1, wherein the substrate comprises the opioid antagonist coated over a core.

Claim 3 (Original): The pharmaceutical formulation of claim 2, wherein the core is a pharmaceutically acceptable inert bead.

Claim 4 (Currently amended): The pharmaceutical formulation of claim 1, wherein the opioid antagonist is dispersed in the substrate comprises matrix multiparticulates having the opioid antagonist dispersed therein.

Claim 5 (Original): The pharmaceutical formulation of claim 1, wherein the opioid antagonist is protonated.

Claim 6 (Original): The pharmaceutical formulation of claim 5, wherein the protonated opioid antagonist has affinity for the anionic polymer.

Claim 7 (Original): The pharmaceutical formulation of claim 1, wherein the anionic polymer is selected from the group consisting of an acrylic polymer, acrylic copolymer, methacrylic polymer, methacrylic copolymer, and mixtures thereof.

Claim 8 (Withdrawn): The pharmaceutical formulation of claim 1, wherein the anionic polymer is a non-acrylic enteric coating material.

Claim 9 (Withdrawn): The pharmaceutical formulation of claim 8, wherein the enteric coating material is selected from the group consisting of cellulose acetate phthalate, hydroxypropyl methylcellulose phthalate, carboxymethyl ethylcellulose, hydroxypropyl methylcellulose acetate succinate, polyvinyl acetate phthalate, cellulose acetate trimellataate, cellulose acetophthalate, cellulose acetate terephthalate, polyvinyl alcohol phthalate, and mixtures thereof.

Claim 10 (Original): The pharmaceutical formulation of claim 1, wherein the diffusion barrier coating is in an amount from about 0.1 to about 10 percent by weight of the substrate.

Claim 11 (Original): The pharmaceutical formulation of claim 1, wherein the opioid antagonist is in a therapeutically effective amount.

Claim 12 (Original): The pharmaceutical formulation of claim 1, comprising a plurality of said substrates.

Claim 13 (Previously Presented): The pharmaceutical formulation of claim 12, wherein said plurality of said substrates comprises a therapeutically effective amount of said opioid antagonist.

Claim 14 (Original): The pharmaceutical formulation of claim 1, wherein the coating comprising

the hydrophobic material provides for the controlled release of the opioid antagonist.

Claim 15 (Cancelled)

Claim 16 (Original): The pharmaceutical formulation of claim 1, wherein the hydrophobic material is selected from the group consisting of a cellulosic material, a cellulosic polymer, an acrylic polymer or copolymer, a methacrylic polymer or copolymer, and mixtures thereof

Claim 17 (Original): The pharmaceutical formulation of claim 1 wherein said opioid antagonist is selected from the group consisting of naltrexone, naloxone and pharmaceutically acceptable salts thereof.

Claim 18-52 (Cancelled)

Claim 53 (Previously presented): The pharmaceutical formulation of claim 17, wherein said opioid antagonist is naltrexone or a pharmaceutically acceptable salt thereof.

Claim 54 (New): The pharmaceutical formulation of claim 1, wherein the erosion promoting agent is a gum.

Claim 55 (New): The pharmaceutical formulation of claim 1, wherein the plasticizer is in amount of from about 1 to about 50 % by weight of the hydrophobic material.

Claim 56 (New): The pharmaceutical formulation of claim 1, wherein the coating comprising the hydrophobic material comprises at least one passageway.

Claim 57 (New): A pharmaceutical formulation comprising:

a substrate comprising a matrix multiparticulate system comprising an opioid antagonist; the substrate overcoated with a diffusion barrier coating consisting of an anionic polymer and at least one optional excipient; and

a coating comprising a hydrophobic material and an erosion-promoting agent, wherein the coating comprising a hydrophobic material is coated over said diffusion barrier coating.

Claim 58 (New): The pharmaceutical formulation of claim 57, wherein the matrix multiparticulate system comprises the opioid antagonist dispersed in a plurality of immediate release matrices.

Claim 59 (New): The pharmaceutical formulation of claim 57, wherein matrix multiparticulate system is a compressed multiparticulate matrix.

Claim 60 (New): The pharmaceutical formulation of claim 57, wherein the opioid antagonist is naltrexone and/or a pharmaceutically acceptable salt thereof.